

REMARKS

Examiner's Love and Blanchard are thanked for granting a personal interview to Robert Goldfarb and the undersigned on January 27, 2010 to discuss the present application. The cited references were discussed as well as an amendment to claim 8 in order to precisely define the two-layered tablet described in the present application. No agreement was reached as to any allowable claim and the Examiners were informed that this response to the outstanding Office Action would be submitted.

The specification has been amended to point out the fact that the present application claims the benefit of PCT/US05/18632, Filed May 23, 2005 which claims the benefit of Serial No. 60/573,042 filed May 21, 2004 and Serial No. 60/573,134, filed May 21, 2004. The original filing receipt, that was mailed, May 9, 2006 recited the claims to priority and In accordance with the Commissioner's Notice of December 30, 2008 regarding Claiming the Benefit of A Prior-Filed Application Under 35 U.S.C. Secs.119(e), 120, 121 and 365(c), cited at 1337 CNOG 739, it is not believed that any Petition is required in support of the amendment to the specification. For these reasons, it is requested that this ground of objection be withdrawn.

Claims 9-11 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

Reconsideration is requested.

Claim 8 has been amended to point out that the distance that the score extends from the top surface of the first segment to the interface is not less than 70% of the distance from the top surface of the first segment to the interface. In addition, claim 8 has been amended to recite that the tablet is one consisting of a first segment having a top surface and a second segment wherein said first segment contains a drug or drugs and a score. The second segment is defined as one that does not contain any pharmacologically effective drug or drugs. An amendment has been made to claim 8 so that there is a proper antecedent basis for the language of amended claim 9. The support for the amendment to claim 9 is found in the specification at page 7, lines 15-25. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 8-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lieberman in view of Ullman et al. and Geller.

Reconsideration is requested.

Lieberman was cited as teaching that it is known to have a tablet wherein the center is free of actives that are incompatible and that Lieberman teaches that it is known to place scores on tablets to allow for manual breakage. The portion relied upon for the teaching of the three layer tablet was on page 274 while page 172 of Lieberman was also cited for its teaching that the purpose of a score was to permit breaking the tablet into equal parts for administration of a half a tablet. The Lieberman teaching

regarding scoring a tablet is unconnected with the Lieberman disclosure of a three layer tablet and there is no teaching that every tablet should be scored. Ullman was applied as teaching deeply scored tablets and Geller was also applied as teaching the concept of scoring a pharmaceutical tablet which was acknowledged in the specification. In addition, the Examiner stated that:

"Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to occur in the inert barrier layer"

It is not seen where Ullman teaches a top and bottom segment where breakage may occur. The tablet of Ullman is a homogeneous tablet and it is not a two layered tablet.

The different considerations that arise from the breaking of a layered tablet versus the breaking of an unlayered tablet point to the unobviousness of the claimed invention as compared to the different concepts set forth in Lieberman, Ullman and Geller. Each of the cited references describe tablet structures that are made differently for different purposes. The concept of the present invention is not found in any of the cited references.

On pages 7 and 8 of the Office Action, the Examiner opined that it would have been obvious to one of ordinary skill in the art to remove one of the drug layers of Lieberman and Ullman should one desire to deliver only one of the actives and that one would have been motivated to retain the barrier layer since the barrier layer "allowed for the

overcoming of the well known problem in the art of variable dosages" (emphasis added).

The quoted section is a recognition of what the present applicant has invented and not what is taught or suggested in the prior art. The deficiency in the rejection is that the cited prior art does not even describe a two layered tablet as defined in amended claim 8 and thus there is no prior art two layered tablet with a score that could be broken through any layer. It can be readily appreciated and understood from the present application, that breaking the tablet through the inert layer provides for very accurate breaking of a tablet. This information is not found in the prior art.

The Examiner's contention that it is obvious to remove an active layer from a three layer tablet, for the purpose of making a tablet with one active layer and one inert layer is not based on a fair reading of the cited references. In addition, this contention is contrary to what a person of ordinary skill in the art would do if he was assigned the task of making a tablet with one active drug and the prior art was the three layer tablet with two incompatible drugs separated by an inert layer. In making a tablet with one active drug, the obvious course of action would be to make a single layer tablet with the desired active and not to deconstruct the three layer tablet by removing one active layer while leaving the inert separating layer behind. This is because once one of the incompatible active drugs has been removed, there is no reason to retain the inert layer because the inert layer no longer serves any function in a tablet

having one active drug. No reference has been cited to even attempt to demonstrate that there are known techniques to take apart three layered compressed tablets which typically have highly coherent layers due to the high compressive forces used to make tablets or that it is obvious to deconstruct three layered tablets.

The present rejection is not based on the contents of the cited reference. No explanation has been given as to where in the references any disclosure is found that tells the skilled artisan to keep a separating layer on a tablet when the reason for its presence no longer exists because there is no incompatible third layer.

It is a fundamental concept in patent law that isolated teachings may not be extracted from a reference and combined with unsupported contentions as to what a skilled person in the art would be motivated to do. In the present case, the prior art used the inert layer for one purpose and only one purpose, namely to separate incompatible active drugs. Since claim 8 excludes any incompatible layer, there is no reason that supports the argument that Lieberman provides a direction or motivation to deconstruct the three layer tablet and retain one active layer with the inert layer.

The only way Lieberman can be interpreted is that the inert layer is used when incompatible layers are to be separated and an inert layer is not used when there are no incompatible layers. No reference has been cited that actually suggests that one should retain an inert separating layer in a three layer tablet when the third incompatible

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layer is removed. In the absence of a reference that teaches the use of a non-functional inert layer in a two layer tablet, as claimed in amended claim 8, it is apparent that the claimed tablet structure is not made obvious by the cited references.

Claim 8 points out a tablet which is distinguishable from Lieberman, Ullman and Geller because claim 8 points out a scored tablet having two segments, one of which has no active ingredient and has a score in the active segment where the score extends at least 70% of the distance to the second segment. This concept is not disclosed or suggested by Lieberman, Ullman or Geller as the tablets disclosed by these references are either three layer tablets or one layer tablets.

The language of claim 8, part (a) points out the claimed tablet consists of two segments which excludes the three layered tablets of Lieberman who does not make a two layered tablet obvious. Geller is only concerned with a single layer tablet and does not disclose the benefit of being able to break a tablet where there is a deeply scored active layer and an inert lower layer which results in a more equal division of the active component.

Geller discloses a pharmaceutical tablet having a score that is "1/3 to 2/3" the depth of the tablet for the purpose of facilitating "separation into subdivisions containing *substantially* equal amounts of pharmaceutically active ingredients". Nothing in Geller discloses a concept of providing "equal" amounts of pharmaceutically active ingredients when a scored tablet is broken along the score as

pointed out in amended claim 8 as well as in claims 9 and 11 which are dependent on claim 8.

As noted above, Claim 8 and the claims that are dependent on claim 8 point out a structure where there are two segments, one of which is inactive and there is a minimum distance into the active layer for the score, where the distance is specified as being at least 70% of the distance from the top surface to the interface between the two segments. There is no reason to modify Lieberman with the Geller score technique because Geller is concerned with making a single layer tablet with one active ingredient and does not suggest a two layered tablet where the score is a minimum of 70% of the distance from the top of the tablet to a second inert segment. If one were to deeply score the Lieberman tablet, one would not obtain the benefits of the deep score taught by Geller. This is evident from the fact that in a three layer tablet, the presence of a deep score would have no effect on the third layer based on the Geller teaching that the score should not extend more than 2/3 of the way through the tablet which in the case of the Lieberman tablet, would not allow the break to occur in the inactive layer.

For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 8-12 were provisionally rejected for obviousness double patenting over copending application Serial No. 10/598,355.

FEB 18 2010

A terminal disclaimer will be filed upon the indication of allowable subject matter to obviate the provisional double patenting rejection.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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